

MEMO

To: [REDACTED]
[REDACTED]

From: Marc Miller
Re: Distributor Review and Translation Risk Management

Distributor Review is frequently employed by medical technology companies to ensure translation quality. However, through the use of an effective, documented translation process that is in conformance with the principles of ISO 13485:2003 and ISO 14971:2000, companies can safely eliminate this costly, time-consuming, and error-prone step.

Background

Definition and Drawbacks

Distributor Review, often termed “Subsidiary Review” or “Overseas Review” is a risk management task that relies on inspection of finished translations by a company’s in-country distributors, subsidiaries, or other subject-specialized, native-language resource. This practice is not mandated under EU regulations, nor is it specified by Notified Body guidance. However, Distributor Review is widely employed as a direct means of providing translation verification.

If review conditions are optimal (the review resource has an expert knowledge of English, his/her native language, the technical subject matter, and the necessary review time) distributor review can provide valuable feedback. However, review conditions are generally not optimal. Often, reviewers do not have the requisite knowledge of the source/target languages nor do they have the required time to adequately review translated materials. Because the review process itself is typically ill-defined, review comments can be stylistic in nature and rather low-value. Finally, since translation review is not a specified part of the reviewer’s job description, this task is often put to the backburner and, when the review deadline arrives, the materials are simply returned to the company with no feedback at all. These common drawbacks mean that Distributor Review, as an effective means for providing translation risk management and verification, can be highly problematic.

Translation Compliance

Currently, there is no process mandated by the EU, the MDD, or the IVDD for minimizing translation risk and ensuring quality. However, labeling in the local language is typically required by the National Implementing Legislation of each EU Member State.

Notified Body guidance indicates the importance of translation quality when it states that companies must “*have procedures for ensuring accurate translation of e.g. labeling, instructions for use and product claims in marketing*”

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material. These are especially important for user instructions where the safety and claimed performance of the device may be compromised through inadequate translation” (NB-MED/2.5.2/Rec3).

And, the importance of translation accuracy is underscored by the risk management standard, ISO 14971. Under ISO 14971, all residual product risk must be mitigated, at a minimum, through labeling and IFUs. Experts at the 2004 RAPS conference (Matthias Buerger, former Notified Body auditor and QA/RA Director for Terumo Heart, Inc; Oliver Christ General Manager for Prosystem AG) have stated that a company may jeopardize its ISO 14971 compliance in overseas markets if a translated IFU is not an accurate reflection of the English language original.

Given the implications for MDD, IVDD, and ISO 14971 compliance, the importance of translation accuracy is clear. However, given the numerous challenges associated with Distributor Review as a means for achieving effective translation risk management and compliance, the solution is less clear. Fortunately, the risk management principles of ISO 14971, combined with the “process approach” of ISO 13485:2003 offer a solution.

Translation Risk Management: Standards & Processes

Process Approach

The adoption of the “Process Approach” is at the heart of the new ISO 13485:2003 (and ISO 9001:2000) quality standard. In the process approach model, process validation and audit takes the place of inspection. In other words, once a process has been validated, routine audit of key control points is sufficient to ensure quality – costly and time-consuming inspection of output can be safely eliminated. This accepted approach forms the basis for a solution to the issues of Distributor Review.

Translation Risk Management Process

According to an opinion letter from KEMA (Notified Body/ISO Registrar), “*identifying and eliminating serious errors is the key translation risk management activity*”. Distributor Review is used as a means to accomplish this goal through inspection. However, due to the reasons noted above, this approach has a significant risk of failure. A more comprehensive methodology, aligned with the principles of ISO 13485 and ISO 14971, enables companies to identify sources of translation risk and design a process to control them. This approach is outlined below:

Translation Risk: Sources & Mitigation

1. Resource Risk – A primary source of translation risk is the selection, maintenance, and audit of translation vendors. A documented SOP for translation vendor selection, maintenance, and audit should contain:
 - a. Translation resources to be screened according to defined criteria (native language, subject matter expertise)
 - b. Resources to be tested using controlled materials and graded according an objective standard, such as the SAE J2450 translation quality metric.
 - c. Documented system in place to ensure routine vendor audit and disqualification when appropriate

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2. Process Risk – The translation process itself must be designed to mitigate risk through the development of adequate reference material and implementation of in-process quality control. An acceptable process would include:
 - a. Project glossary development and in-country glossary review. Distributor review of project glossaries ensures that correct technical terminology is utilized, that distributor comments are restricted to technical terms (more valuable, less time consuming), and that in-country sources remain involved in the overall process.
 - b. Initial translation by approved resource (see above)
 - c. Linguistic verification (edit) by second approved resource (not the original translator)
 - d. Linguistic QA by resource with native fluency in the source language (to ensure semantic accuracy). Ideally, this QA step is audited according to an objective standard such as the SAE J2450 translation quality metric
 - e. To guard against “Process Fraud”, documentation specifying tasks/resources for all required process steps

Additionally, since the formatting activity can significantly impact the quality of a translated document, formatting QA (by approved resources) must be part of the process whenever translation services include layout. Formatting QA resources must be tested and approved according to a documented process.

Conclusion

Distributor Review is often used by medical technology companies as an inspection QA method for translated materials. However, if a company’s translation process includes the risk management processes noted above, then the inspection step of Distributor Review may be safely omitted.



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